

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 05/22/2013

SUBJECT: Prothioconazole: Submission of Conditional Data Requirements on Storage Stability and Analytical Methods of Plants and Ruminants.

PC Code: 113961

Decision No.: 471191

Petition No.: NA

Risk Assessment Type: NA

TXR No.: NA

MRID No.: NA

DP Barcode: D407465

Registration No.: NA

Regulatory Action: Amended Section 3

Case No.: NA

CAS No.: 178928-70-6

40 CFR: §180.626

FROM: Meheret Negussie, Chemist *Meheret Negussie*
Risk Assessment Branch III (RAB III)
Health Effects Division (HED) (7509P)

THRU: Steve Funk, Senior Chemist *Steve Funk*
Christine Olinger, Branch Chief *Christine Olinger*
Risk Assessment Branch III (RAB III)
Health Effects Division (7509P)

TO: Tony Kish, Risk Manager
Rosemary Kearns, Risk Manager Reviewer
Fungicide Branch
Registration Division (7505P)

I. CONCLUSIONS/RECOMMENDATIONS

As a condition of registration in PP# 4F6830, Bayer CropScience (BCS) was required to submit storage stability data for residues of prothioconazole and revise analytical methods for plants and ruminants to include two ion transitions (S. Funk, D379587, 01/31/11). The requested storage stability data has been submitted and found to satisfy this condition of registration. Acceptable storage stability data were provided demonstrating that prothioconazole is stable in plants stored frozen for ~ 45 months. The requested revisions to the analytical methods are still outstanding.

BCS has requested additional time to generate data to satisfy the deficiency; HED has no objection to the request.

II. RESULTS/DISCUSSION

Storage Stability

In conjunction with PP#4F6830 (DP# 303508 & D314517, 08/21/06), the final report of the ongoing storage stability study with prothioconazole and desethio-prothioconazole in plant commodities (interim results for which were reported in MRID 46477701) were requested to be submitted as confirmatory data.

BCS conveyed that the samples from the ongoing storage stability study with prothioconazole and desethio-prothioconazole were discarded after the analysis of the 36-month storage interval.

To support storage stability of residues of prothioconazole for up to 45 months, BCS has submitted residue data of re-analyses at 30-46 months of canola, barley, dried peas, and wheat field trial samples that were stored for 18-32 months before analyses (MRID 48938301). Residue data for these samples were previously submitted with the request to establish tolerances.

The data submitted represent three of the five commodity categories required for storage stability demonstration: high oil content (canola), high protein content (dry pea), high starch content (barley grain). High water content and high acid content commodities are not represented. However, these categories are not relevant to the existing prothioconazole tolerances. Additional storage stability data will be needed if registrations are pursued for use on high water and/or high acid content commodities.

Comparison of the total residues of the re-analyzed samples stored for 30-46 months with the samples stored for 18-32 months indicated that total residues were in the range of 73-119% (average 99%) of the residues stored for 18-32 months. Overall the % degradation was below 10%, with two exceptions 22% and 27%. The maximum storage stability interval demonstrated was 46 months. These results indicated that total prothioconazole is stable in plants up to 45 months of frozen storage. No raw data (chromatograms) was submitted. The results are summarized in Table 1.

Residue Analytical Methods

In conjunction with PP#4F6830 (DP# 303508 & D314517, 08/21/06), revisions of the enforcement methods, LC/MS/MS Method RPA JA/03/01 for crop commodities and LC/MS/MS Method Bayer Report No. 200537 for ruminant commodities, were required to include at least two ion transitions to preclude the need for a confirmatory method.

BCS is proposing multiple ion transitions that could be used to determine prothioconazole residues in plants and ruminants. BCS conveyed that they will submit the revised methods that

include the proposed ion transitions. BCS also communicated that currently no validation data for the two ion transitions is available and is requesting for additional time to generate the data. The revisions of these methods should be submitted. The analytical method deficiency remains outstanding.

Table 1. Summary of Freezer Storage Stability Data from Reanalysis of Samples from the Prothioconazole Field Crop Residue Studies on Canola, Barley, Peas, and Wheat.

Sample No.	Matrix	Storage Interval Months	Total Residues (ppm) ¹	Storage interval	Total Residues ¹	% of Residues Found at 18-32 months	% Degradation
Canola							
J6130-00HA-002	Seed	29	0.074	41	0.070	95	5
J6130-00HA-003	Seed		0.097		0.076	78	22
Average							14
Barley							
J6003-00H-002	Hay	32	1.814	46	1.777	98	2
J6003-00H-003	Hay		1.741		1.621	93	7
J6004-00H-002	Hay		2.577		2.361	92	8
J6004-00H-003	Hay		1.668		1.676	100	0
Average							4
J6003-00H-008	Straw	32	1.336	45	1.615	121	0
J6003-00H-009	Straw		1.321		1.514	115	0
J6004-00H-008	Straw	31	1.324	44	1.36	103	0
J6004-00H-009	Straw		1.269		1.241	98	2
Average							1
J6003-00H-005	Grain	32	0.088	45	0.084	95	5
J6003-00H-006	Grain		0.082		0.096	117	0
J6004-00H-005	Grain	30	0.059	44	0.068	115	0
J6004-00H-006	Grain		0.083		0.099	119	0
Average							1
Dried Peas							
J6007-02H-003	Peas	18	0.12	30	0.11	92	8
J6007-02H-004	Peas		0.122		0.115	94	6
J6008-02H-003	Peas		0.102		0.107	105	0
J6008-02H-004	Peas		0.118		0.109	92	8
Average							5
Wheat							
J6045-00D-005	Forage	30	1.827	46	1.335	73	27
J6045-00D-006	Forage		1.383		1.426	103	0
J6045-00D-008	Forage		45	0.273	0.255	93	7
J6045-00D-009	Forage			0.325	0.249	77	23
Average							14
J6058-00H-005	Hay	31	0.71	46	0.794	112	0
J6058-00H-006	Hay		1.063		1.146	108	0
J6064-00H-005	Hay	30	1.928	45	2.134	111	0
J6064-00H-006	Hay		2.501		2.546	102	0
Average							0
J6058-00H-011	Straw	30	0.93	46	0.923	99	1
J6058-00H-012	Straw		1.053		0.948	90	10
Average							5

¹ Sum of prothioconazole and desethio-prothioconazole, expressed as prothioconazole.